

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12483



2 - LABEL SAMPLE

000001

DIRECTIONS:

Take one to two capsules
daily 30 minutes before
each meal with water.

ShapeRite®

©1996 Sandy, Utah 84070

SHAPERITE®

SHAPE-FAST

Plus

FAT BURNING FORMULA*

90 capsules

INGREDIENTS:

Each 400mg Kosher gelatin capsule contains ma
huang (standardized to 15mg ephedra alkaloids), Bio-
Trim (proprietary blend of Citris aurantium, Salix pur-
purea, and pantothenic acid), Fucus vesticulosis, Cola
acuminata, NDS†, an 40mg caffeine. [kosher symbol]

WARNING: Seek advise from a healthcare practioner prior
touse if you are pregnant, nursing or if you have high blood
pressure, heart or thyroid disease, diabetes, hypoglycemia,
difficulty in urination due to prostate enlargement or if you
are taking an MAO inhibitor or any other prescription drug.
Reduce or discontinue use if nervousness, tremors, sleep-
lessness, loss of appetite or nausea occur. Not for use by
people under age 18. KEEP OUT OF REACH OF CHILDREN.

†ShapeRite's proprietary blend of digestive enzymes

*This statement has not been evaluated by the Food &
Drug Administration. This product is not intended to diag-
nose, treat, cure or or prevent any disease.

product code 1020

PS0787

Verified
8/5/97 TSB

000002

1. FLAG SURVEILLANCE <input type="checkbox"/> COMPLIANCE <input checked="" type="checkbox"/> CONSUMER COMPLAINT INJURY				2. TYPE SAMPLE		3. SAMPLE NUMBER 97-757-340													
4. CENTRAL FILE NUMBER 1722000		5. DATE COLLECTED 7-31-97		6. PRODUCT CODE 54FCE09		7. RESPONSIBLE FIRM M													
10. RELATED SAMPLE NONE		11. PC 2		12. COLL NO. 144		13. SPLING DISTRICT LOS-DO													
				14. COLL DISTRICT LOS-DO		8. PROGRAM ASSIGNMT CODE 03R801													
						9. HOURS 4													
15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) BROWNISH COLORED HARD GEL CAPS IN PLIO SNAPCAP BOTTLE LABL'D IN PART "SHAPERITE SHAPE-FAST Plus FAT BURNING FORMULA* 90 capsules DIRECTIONS: Take one to two capsules daily 30 minutes before each meal with water ***INGREDIENTS: Each 400 mg Kosher gelatin capsule contains ma huang (standardized to 15mg ephedra alkaloids),***Cola acuminata,***and 40mg caffeine.***product This product is not intended to diagnose, treat, cure or prevent any disease***product code 1020PS0787***ShapeRite 1996 Sandy, Utah 84070***".																			
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) F/Uto consumer complaint involving injury check for ephedra .						17. MFG CODES (Labels, pkg, shipping containers) "PS0787"													
18. MANUFACTURER (Name, address & ZIP) ShapeRite Sandy, UT. 84070				19. SHIPPER (Name, address & ZIP) presumed same as manuf.		20. DEALER (Name, address, ZIP & TELEPHONE) <div style="background-color: black; width: 100px; height: 50px;"></div>													
21. SIZE OF LOT FROM WHICH SAMPLED one opened container containing 64 capsules				22. EST VALUE		23. RECEIPT ISSUED <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>FDA472</td> <td>FDA484</td> <td>NONE</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">x</td> </tr> </table>		FDA472	FDA484	NONE			x						
FDA472	FDA484	NONE																	
		x																	
24. DATE SHIPPED & DOC REF not determined at this time																			
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) One opened container that injured party was using at time of incident provided by husband. contains 64 of the original 90 capsules.																			
26. HOW PREPARED Bottle identified and FDA sealed in paper bag for FED'X to laboratory																			
27. COLLECTOR'S IDENT ON PKG AND/OR LABEL "97-757-340 7-31-97 JAN"				28. COLLECTOR'S IDENTIFICATION ON SEAL "97-757-340 8-1-97 John A. Nicholson"															
29. SAMPLE DELIVERED TO Federal Express 8-1-97 (Phoenix)				30. DATE DELIVERED 8-1-97		31. LAB SEA-DO													
				32. LAB WITH SPLIT SAMPLE		33. ORIG C/R & RECORDS TO LOS-DO													
34. RCDS OBTAINED	a. INVOICE NO. AND DATE not available at collection			b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc.) NO. AND DATE none collected at this time															
	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE																		
35. REMARKS (If additional space is needed, attach form FDA 464a, C/R Continuation Sheet) refer to 2516 LOS-6749																			
36. CONSUMER CMPLAINT NO. OR RECALL NO. LOS-6749		37. AMT. \$ <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>CRED CD</td> <td>C</td> <td>V</td> <td>B</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>		CRED CD	C	V	B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38. 704(d) SPL <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>YES</td> <td>NO</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </table>		YES	NO	<input type="checkbox"/>	<input checked="" type="checkbox"/>	39. COLLECTOR (Typed name and signature) John A. Nicholson, 144	
CRED CD	C	V	B																
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
YES	NO																		
<input type="checkbox"/>	<input checked="" type="checkbox"/>																		

FORM FDA 464 (11/85) PREV ED MAY BE USED.

COLLECTION REPORT

CIRCLE APPROPRIATE COPY:

SAMPLE RECORD **COPY 1** (White) HOME DISTRICT **COPY 2** (Pink) COLLECTING DISTRICT **COPY 3** (Green)
 SAMPLE RECORD **COPY 4** (Samon) COLLECTING DISTRICT MONITOR **COPY 5** (Blue) COLLECTOR'S **COPY 6** (Yellow)

000003

12483.

1. PRODUCT Shaperite Shape-Fast Plus		2. SAMPLE NO. 97-757-340																	
3a. SAMPLE CLASSIFICATION (Insert classification code for each PAC represented by sample)		3b. LABORATORY CONCLUSIONS Sample consisted of one opened bottle of product containing 64 capsules. Sample analyzed for ephedra alkaloids by LIB 3996. Results: <table><thead><tr><th></th><th><u>mg/g</u></th><th><u>mg/cap</u></th><th></th></tr></thead><tbody><tr><td>Ephedrine</td><td>23.5</td><td>12.0</td><td></td></tr><tr><td>Pseudoephedrine</td><td>trace</td><td>trace</td><td></td></tr><tr><td>Total alkaloids</td><td>23.5</td><td>12.0</td><td>= 80% of declared (15 mg/capsule declared)</td></tr></tbody></table>			<u>mg/g</u>	<u>mg/cap</u>		Ephedrine	23.5	12.0		Pseudoephedrine	trace	trace		Total alkaloids	23.5	12.0	= 80% of declared (15 mg/capsule declared)
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CODE	PAC NO.																		
4	03R801																		
3c. NAME AND TITLE - Julie A. Rorberg, Chemist		3d. SIGNATURE <i>Julie A. Rorberg</i>	3e. DATE 8/7/97																
4a. DISTRICT CONCLUSIONS																			
4b. NAME AND TITLE (District)		4d. SIGNATURE	4e. DATE																

FORM FD 465

SAMPLE SUMMARY

98 MAY 18 AM 1:41

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSM HFS-452

000004